

Special 510(k) Premarket Notification  
 GE Medical Systems - LOGIQ 5 Pro/Expert Ultrasound System  
 September 23, 2003

OCT 21 2003

**Attachment B:**  
*Summary of Safety and Effectiveness*  
*Prepared in accordance with 21 CFR Part 807.92(c).*



GE Ultrasound

GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC  
 4855 West Electric Avenue  
 Milwaukee, WI 53219

**Section a):**

1. **Submitter:** GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC  
 PO Box 414  
 Milwaukee, WI 53201  
  
**Contact Person:** Allen Schuh,  
 Manager, Safety and Regulatory Engineering  
 Telephone: 414-647-4385; Fax: 414-647-4090  
  
**Date Prepared:** September 23, 2003
2. **Device Name:** GE LOGIQ 5 Pro/Expert Diagnostic Ultrasound System  
 Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
3. **Marketed Device:** GE LOGIQ 5 diagnostic ultrasound system, 510(k) Numbers K014097 currently in commercial distribution.
4. **Device Description:** The GE LOGIQ 5 is a full featured general purpose diagnostic ultrasound system available in Expert (full featured) or Pro (reduced feature) versions. Both versions consists of a mobile console approximately 52 cm wide, 99 cm deep and 135 cm high that provides digital image acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, color video CRT display and LCD touch screen. The modification adds coded pulse modes from high-end LOGIQ systems to the Expert version and removes provides limited options for the Pro version.
5. **Indications for Use:** The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, vascular and neurological).
6. **Comparison with Predicate Device:** The GE LOGIQ 5 Pro & Expert versions are comparable with and substantially equivalent to the current GE LOGIQ 5. They have the same technological characteristics, are comparable in key safety and effectiveness features, utilize the same overall design, construction, and materials, and have the same intended uses and basic operating modes as the predicate device.

**Section b):**

1. **Non-clinical Tests:** The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. **Clinical Tests:** None required.
3. **Conclusion:** Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE LOGIQ 5 Pro/Expert Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 21 2003

Mr. Allen Schuh  
Manager, GE Ultrasound Safety  
GE Medical Systems  
Ultrasound and Primary Care Diagnostics, LLC  
4855 West Electric Avenue  
MILWAUKEE WI 53219

Re: K032974  
Trade Name: GE LOGIQ 5 Pro/Expert Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: 90 IYN, IYO, and ITX  
Dated: September 23, 2003  
Received: September 24, 2003

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ 5 Pro/Expert Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C  
3.5C

3.5Cs

5C

8C

E8C

BE9C

7L

10L

12L

i12L

3S

7S

10S

6T

P2D

P6D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

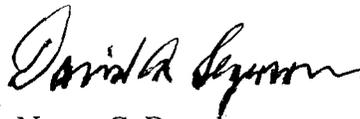
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



*for*

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P		
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular	P	P	P	P	P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal	P	P	P		P		P	P			
Transvaginal	P	P	P		P		P	P			
Transurethral											
Intraoperative <sup>[5]</sup>	P	P	P		P		P	P			
Intraoperative Neurological	P	P	P		P		P	P			
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

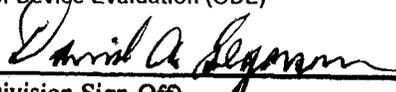
[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 3C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P		P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

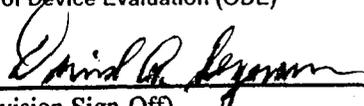
Notes: [1] Abdominal includes GYN;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 3.5C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	E	E	E		E	E	E	E	E	N	
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E	E	N	
Pediatric											
Small Organ (specify)	E	E	E		E	E	E	E	E	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E	E	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	E	E	E		E	E	E	E	E	N	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

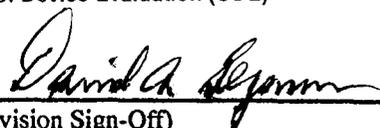
Notes: [1] Abdominal includes GYN;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 3.5Cs Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	E	E	E		E	E	E	E	E	N	
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E	E	N	
Pediatric											
Small Organ (specify)	E	E	E		E	E	E	E	E	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E	E	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	E	E	E		E	E	E	E	E	N	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

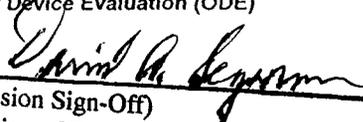
Notes: [1] Abdominal includes GYN;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K032974

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 5C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P			
Abdominal <sup>[1]</sup>	P	P	P		P		P	P			
Pediatric	P	P	P		P		P	P			
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P		P	P			
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

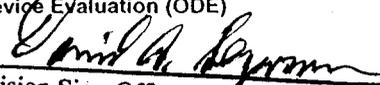
Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[4] Other includes urology

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E	E	N		
Pediatric	E	E	E		E	E	E	E	E	N		
Small Organ (specify)	E	E	E		E	E	E	E	E	N		
Neonatal Cephalic	E	E	E		E	E	E	E	E	N		
Adult Cephalic												
Cardiac												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>												
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

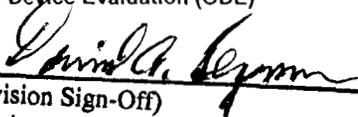
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic;

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with E8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics	P	P	P		P		P	P	N	N
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	N	N
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other <sup>[4]</sup>	P	P	P		P		P	P	N	N
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal	P	P	P		P		P	P	N	N
Transvaginal	P	P	P		P		P	P	N	N
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

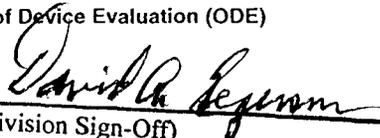
Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032994

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with BE9C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics	E	E	E		E		E	E	N	N		
Abdominal <sup>[1]</sup>	E	E	E		E		E	E	N	N		
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>	E	E	E		E		E	E	N	N		
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal	E	E	E		E		E	E	N	N		
Transvaginal	E	E	E		E		E	E	N	N		
Transurethral												
<i>Intraoperative (specify)</i>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

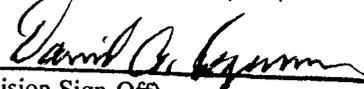
Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 7L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics	E	E	E		E	E	E	E	E	N		
Abdominal	E	E	E		E	E	E	E	E	N		
Pediatric												
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E	E	N		
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Peripheral Vascular	E	E	E		E	E	E	E	E	N		
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	N		
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	N		
Other <sup>[4]</sup>												
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

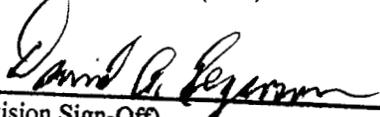
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 10L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P		N	
Abdominal											
Pediatric	P	P	P		P		P	P		N	
Small Organ <sup>[2]</sup>	P	P	P		P		P	P		N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P		N	
Musculo-skeletal Conventional	P	P	P		P		P	P		N	
Musculo-skeletal Superficial	P	P	P		P		P	P		N	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[5]</sup>	P	P	P		P		P	P		N	
Intraoperative Neurological	P	P	P		P		P	P		N	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

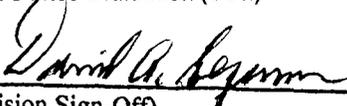
Notes: [2] Small organ includes breast, testes, thyroid.

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P		P	P	P	N	
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	N	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	N	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	N	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[5]</sup> (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

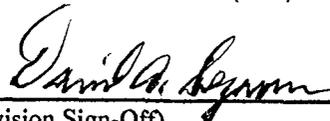
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number     K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with i12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E				
Pediatric	E	E	E		E	E	E	E				
Small Organ (specify)	E	E	E		E	E	E	E				
Neonatal Cephalic												
Adult Cephalic												
Cardiac <sup>[3]</sup>	E	E	E		E	E	E	E				
Peripheral Vascular	E	E	E		E	E	E	E				
Musculo-skeletal Conventional	E	E	E		E	E	E	E				
Musculo-skeletal Superficial	E	E	E		E	E	E	E				
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative <sup>[5]</sup>	E	E	E		E	E	E	E				
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal is via Intraoperative;

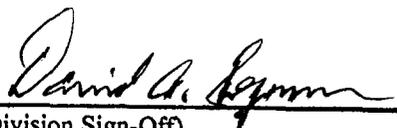
[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 3S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P	P	P	
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

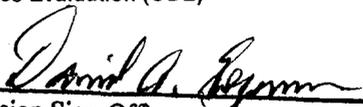
[3] Cardiac is Adult and Pediatric;

[4] Other use includes Urology;

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 7S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P	P		
Small Organ (specify)												
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P		
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

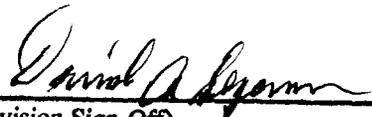
Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 10S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal	E	E	E	E	E	E	E	E	E		
Pediatric	E	E	E	E	E	E	E	E	E		
Small Organ (specify)											
Neonatal Cephalic	E	E	E	E	E	E	E	E	E		
Adult Cephalic	E	E	E	E	E	E	E	E	E		
Cardiac <sup>[3]</sup>	E	E	E	E	E	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

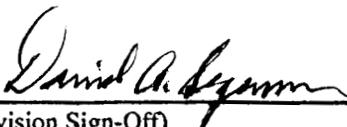
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with 6T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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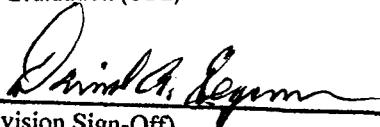
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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K032974    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>				E							
Peripheral Vascular				E							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Epperson*

(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number     K032974

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ 5 Pro/Expert with P6D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac <sup>[3]</sup>					P							
Peripheral Vascular					P							
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.

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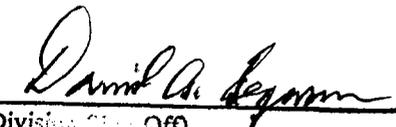


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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

  
 (Division Chief, Off)  
 Div \_\_\_\_\_, \_\_\_\_\_, Abdominal,  
 and \_\_\_\_\_ Services  
 510(k) Number K032974